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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,871	11/05/2003	Renfeng Guo	UM-08443	6716

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/701,871	GUO ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *040907*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO APPLICASNTS' AMENDMENT

Applicants' Amendment

1) Acknowledgment is made of Applicants' amendment filed 04/09/07 in response to the non-final Office Action mailed 01/09/07.

Status of Claims

2) Claims 28 and 30 have been canceled via the amendment filed 04/09/07.

Claim 26 has been amended via the amendment filed 04/09/07.

Claims 26 and 27 are pending and are under examination.

Information Disclosure Statement

3) Acknowledgment is made of Applicants' information disclosure statement filed 04/09/07. Except for the unobtainable US 20020350961 document, the information referred to therein has been considered and a signed copy is attached to this Office Action.

Prior Citation of Title 35 Sections

4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

6) The objection to the specification made in paragraph 7 of the Office Action mailed 01/09/07 is withdrawn in light of Applicants' amendment to the specification.

Rejection(s) Moot

7) The provisional rejection of claims 28 and 30 made in paragraph 9 of the Office Action mailed 01/09/07 under the judicially created doctrine of obviousness-type double patenting over claims 2 and 4-7 of the co-pending application 11/236,188, is moot in light of Applicants' cancellation of the claims.

8) The rejection of claims 28 and 30 made in paragraph 10 of the Office Action mailed

01/09/07 under the judicially created doctrine of obviousness-type double patenting over claims 1-4 of the U.S patent 6,866,845 is moot in light of Applicants' cancellation of the claims.

9) The rejection of claim 28 made in paragraph 12 of the Office Action mailed 01/09/07 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

10) The rejection of claim 28 made in paragraph 14 of the Office Action mailed 01/09/07 under 35 U.S.C § 102(b) as being anticipated by Strachan *et al.* (*J. Immunol.* 164: 6560-6565, 2000 – Applicants' IDS), is moot in light of Applicants' cancellation of the claim.

11) The rejection of claim 28 made in paragraph 15 of the Office Action mailed 01/09/07 under 35 U.S.C § 102(a) as being anticipated by Huber-Lang *et al.* (*The FASEB J.* 16: 1567-1574, October 2002), is moot in light of Applicants' cancellation of the claim.

12) The rejection of claim 30 made in paragraph 15 of the Office Action mailed 01/09/07 under 35 U.S.C § 102(b) as being anticipated by Larrick *et al.* (EP 0 245 993 A2) as evidenced by Huber-Lang *et al.* (*The FASEB J.* 16: 1567-1574, October 2002), is moot in light of Applicants' cancellation of the claim.

Rejection(s) Withdrawn

13) The provisional rejection of claims 26 and 27 made in paragraph 9 of the Office Action mailed 01/09/07 under the judicially created doctrine of obviousness-type double patenting over claims 2 and 4-7 of the co-pending application 11/236,188, is withdrawn in light of Applicants' amendment to the base claim.

14) The rejection of claims 25 and 27 made in paragraph 10 of the Office Action mailed 01/09/07 under the judicially created doctrine of obviousness-type double patenting over claims 1-4 of the U.S patent 6,866,845, is withdrawn in light of Applicants' amendment to the base claim.

15) The rejection of claims 26 and 27 made in paragraph 14 of the Office Action mailed 01/09/07 under 35 U.S.C § 102(b) as being anticipated by Strachan *et al.* (*J. Immunol.* 164: 6560-6565, 2000 – Applicants' IDS), is withdrawn in light of Applicants' amendment to the base claim.

16) The rejection of claims 26 and 27 made in paragraph 15 of the Office Action mailed 01/09/07 under 35 U.S.C § 102(a) as being anticipated by Huber-Lang *et al.* (*The FASEB J.* 16: 1567-1574, October 2002), is withdrawn in light of Applicants' amendment to the base claim.

17) The rejection of claims 26 and 27 made in paragraph 16 of the Office Action mailed 01/09/07 under 35 U.S.C § 102(b) as being anticipated by Larrick *et al.* (EP 0 245 993 A2) as evidenced by Huber-Lang *et al.* (*The FASEB J.* 16: 1567-1574, October 2002), is withdrawn in light of Applicants' amendment to the base claim.

New Rejection(s) Necessitated by Applicants' Amendment

Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)

18) Claim 26, and the claim that depends therefrom, are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 26, as amended, includes the added limitation: 'said reagent comprises a monoclonal antibody that specifically binds to said C5a receptor'. This means that the scope of the claim includes a reagent capable of blocking a C5a receptor wherein said reagent 'comprises' within it said monoclonal antibody. The term 'comprises' allows the inclusion any other active element in addition to the recited monoclonal antibody. However, there appears to be no descriptive support in the specification, as originally filed, for this added limitation. Applicants do not point to specific parts of the specification that provide descriptive support for the new limitations. While lines 19 and 20 of page 4 and lines 22-23 of page 7 of the specification provide descriptive support for a reagent as recited wherein the reagent 'is a monoclonal antibody' that specifically binds to said C5a receptor, the specification is not supportive of a 'reagent that comprises a monoclonal antibody that specifically binds to said C5a receptor' as recited currently. Therefore, the above-identified limitation in the claim is considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are invited to point to specific line and page numbers of the specification, as originally filed, that provide descriptive support for the limitations identified above, or alternatively, remove the new matter from the claim. Applicants should specifically point out the support for any amendment made to the disclosure. See MPEP 714.02 and 2163.06.

Rejection(s) under 35 U.S.C. § 102

19) Claims 26 and 27 are rejected under 35 U.S.C § 102(b) as being anticipated by Morgan *et al.* (US 5,480,974 – Applicants' IDS).

Morgan *et al.* taught a method of treating an immunopathological disease or disorder such as gram negative bacterial sepsis or ARDS which is associated with the C5aR comprising administering to a patient already evidencing active sepsis an immunotherapeutically effective amount of a C5aR-specific antibody to ameliorate the disorder. The method lessens the severity of gram negative bacterial sepsis. See the second full paragraph under 'Summary of the Invention' and the first, third and fourth full paragraphs under 'Detailed Description of the Invention'. The C5aR-specific antibody is a monoclonal antibody including the 6G4 monoclonal antibody, which blocks C5aR. See the third full paragraph in column 4; abstract; the paragraph bridging columns 4 and 5; the third full paragraph in column 5; the fifth and sixth full paragraphs in column 7; the paragraph bridging columns 7 and 8; the second full paragraph in column 8; the fourth and fifth full paragraphs in column 10; the paragraph bridging columns 10 and 11; the first, second and third full paragraphs in column 11; and Example 7.

Claims 26 and 27 are anticipated by Morgan *et al.*

Rejection(s) under 35 U.S.C. § 103

20) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person. having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

21) Claims 26 and 27 are rejected under 35 U.S.C § 103(a) as being unpatentable over

Riedemann *et al.* (*J. Clin. Invest.* 110: 101-108, July 2002 – Applicants' IDS) in view of Werfel *et al.* (*J. Immunol.* 157: 1729-1735, 1996) or Rothermel *et al.* (*Scand. J. Immunol.* 52: 401-410, 2000) and Behnke *et al.* (US 5,573,921).

Riedemann *et al.* taught a method of treating mice suffering from sepsis comprising administering to said mice an anti-C5aR polyclonal antibody that blocks C5aR which method resulted in a significant overall 7-day survival of 76% compared to control mice that were treated with normal IgG which showed an overall survival of 0% by day 5. The anti-C5aR antibody treatment of septic mice significantly reduced IL-6 and TNF-alpha levels and a significant reduction of aerobic bacterial counts in the lungs and kidneys when compared with control IgG-treated mice. See paragraph bridging pages 105 and 106; Figures 6 and 7; and first full paragraph in right column of page 102.

The method of Riedemann *et al.* differs from the instant invention in that the antibody administered is not a monoclonal antibody.

However, the monoclonal antibodies that bind specifically to C5a receptor (C5aR) were already known in the art at the time of the invention. For instance, Werfel *et al.* taught five anti-C5aR monoclonal antibodies (see abstract).

Similarly, Rothermel *et al.* taught the monoclonal antibody R63 that binds to C5aR. See abstract; paragraph bridging the two columns on page 402 and on page 407; and paragraph bridging pages 403 and 404.

Behnke *et al.* disclosed the numerous advantages of monoclonal antibodies over polyclonal antibodies by teaching that monoclonal antibodies can be obtained in large amounts and at a high degree of purity; the mAbs are homogeneous in terms of the antigen reactivity and their properties are the same in each batch prepared; and hybridoma cell lines from which they are produced can be stored for several years without loosing their specific properties. See lines 9-17 in column 2.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to replace the anti-C5aR polyclonal antibody in Riedemann's method with the already art-known Werfel's or Rothermel's anti-C5aR monoclonal antibody to produce the method of the instant invention with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to produce the instant invention for the expected benefit of providing abundant amounts of anti-C5aR antibodies of high purity and homogeneous antigen reactivity as

taught by Behnke *et al.* Replacement on one art-known antibody having specific binding to C5aR with another, alternative, art-known antibody having the same specificity was well within the realm of routine experimentation, would have been obvious to one of ordinary skill in the art, and would have brought about similar results or effects.

Claims 26 and 27 are *prima facie* obvious over the prior art of record.

Remarks

22) Claims 26 and 27 stand rejected.

23) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

24) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

25) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

26) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached

on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

June, 2007

S. DEVI, PH.D.
PRIMARY EXAMINER